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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,096	02/01/2001	Dan Nilsson	54337.000009	6906
21967	7590	10/01/2004	EXAMINER	
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 10/01/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/720,096	<b>Applicant(s)</b> NILSSON ET AL.	
	<b>Examiner</b> David J Steadman	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,9-14,17,24 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,9-14,17,24 and 26-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Application***

- [1] Claims 1, 9-14, 17, 24, and 26-32 are pending in the application.
- [2] Applicants' amendment to the claims, filed July 21, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicant's arguments filed July 21, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Claim Objections***

- [5] In view of the amendment to the claims, the objection of claim 6 as set forth in item [7] of the Office action mailed May 04, 2004 is withdrawn.
- [6] Claim 24 is grammatically incorrect in the recitation of "a milk" (line 3). It is suggested that applicants replace "a milk" with "milk" or "a milk product." Appropriate correction is required.
- [7] Applicant is advised that should claim 1 be found allowable, claims 26 and 27 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112, Second Paragraph***

[8] In view of applicant's amendment to claim 1, the rejection under 35 USC 112, second paragraph as set forth in item [9] of the Office action mailed May 04, 2004 is withdrawn.

[9] Claims 1, 9-14, 17, 24, and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 1 (claims 9-14, 17, and 32 dependent therefrom), 24, 26-27, and 31 are unclear in the recitation of "conditions where the bacterial starter culture is metabolically active." From the specification, it appears that in order that the milk be "substantially unaffected by the bacteriophage," it is necessary for the milk to be kept under conditions where the bacterial starter culture is metabolically active, *but is not capable of DNA replication, RNA transcription, or protein synthesis* in step (iii). As written, it is unclear as to whether the "conditions where the bacterial starter culture is metabolically active" are conditions where the bacterial starter culture is or is not capable of DNA replication, RNA transcription, or protein synthesis. It is suggested that applicants clarify the meaning of the claims.

**[b]** Claim 11 recites the limitation "the material" (line 3). There is insufficient antecedent basis for this limitation in the claims. It is suggested that the claim be amended to replace "the material" with, for example, "the milk."

**[c]** Claim 24 recites the limitation "the modified lactic acid bacterium" (lines 3-4). There is insufficient antecedent basis for this limitation in the claims.

**[d]** Claims 28-29 are confusing as the claims are dependent upon canceled claims 4 and 5. It is suggested that applicants correct the dependency of the claims.

**[e]** Claim 30 is incomplete as the claim is drawn to "[a] method for keeping the capability to a bacterial strain to ferment milk even in the presence of a bacteriophage," however, from the disclosure it appears that in order for the bacterial strain to ferment milk in the presence of a bacteriophage, the bacterial strain must have metabolic activity in milk, but be incapable of DNA replication, RNA transcription or protein synthesis. It is unclear from the claim as to whether the bacterial strain is metabolically active when added to the milk, whether the strain is incapable of DNA replication, RNA transcription or protein synthesis in the presence of the milk, and whether the strain has the ability to ferment milk in the presence of a bacteriophage. It is suggested that applicants clarify the meaning of the claim.

**[f]** Claim 31 is confusing as the preamble of the claim recites, "adding a purine or thymidine auxotrophic bacterial starter culture to a dairy flavouring," however, it is unclear from parts (i), (ii), and (iii) of the claim as to whether the "bacterial strain which is not capable of DNA replication, RNA transcription or protein synthesis" is meant to be limited to a purine or thymidine auxotrophic bacterial starter culture. In the interest of

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compact prosecution, the examiner has interpreted the claim as though the "isolated bacterial strain" or "bacterial culture" as recited in parts (i), (ii), and (iii) of claim 31 were limited to a "purine or thymidine auxotrophic" bacterial strain or culture as suggested in the preamble and end of the claim. It is suggested that applicants clarify the meaning of the claim.

***Claim Rejections - 35 USC § 112, First Paragraph***

**[10]** In view of applicants' amendment, the written description rejection of claims 1-3, 6-7, 9-11, 24, 26-27, and 30-32 under 35 U.S.C. 112, first paragraph, as set forth at item [10] of the Office action mailed May 04, 2004 is withdrawn.

**[11]** The written description rejection of claims 12-14 and 17 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [10] of the Office action mailed May 04, 2004 and for the reasons stated below.

**[12]** RESPONSE TO ARGUMENTS: Applicants argue the claims have been limited to a purine or thymidine auxotrophic bacterial culture. Applicants' argument is not found persuasive.

While the bacterial strain/culture of claim 1 has been limited to a purine or thymidine auxotrophic bacterium, the specification fails to describe the genus of genetically modified strains or bacterial strains that are capable of increasing cell size without mitosis as encompassed by claims 12-14 and 17. In this case, the specification fails to disclose even a single representative species of the genus of genetically modified strains enhanced in at least one metabolic pathway (claims 12-14) or a

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bacterial strain that is capable of increasing cell size without mitosis (claim 17). It is the examiner's position that the specification fails to disclose a representative number of species of the genus of genetically modified strains, bacterial strain that is capable of increasing cell size without mitosis, or bacterial strains that are not capable of DNA replication, RNA transcription, or protein synthesis. At least for this reason, the specification fails to describe the recited genus of bacterial strains.

**[13]** In view of applicants' amendment to the claims to limit the bacterial strain/culture used in the fermentation of milk, milk product, dairy flavoring, or product for cheese flavoring to a purine or thymidine auxotrophic bacterium, the scope of enablement rejection of claims 1-7, 9-11, 24, and 26-32 under 35 U.S.C. 112, first paragraph, as set forth at item [11] of the Office action mailed May 04, 2004 is withdrawn. Upon review of the specification for enablement of the claimed methods, the examiner has raised the new scope of enablement rejection below. It should be noted that, to the extent the scope of enablement rejection as set forth at item [11] of the Office action mailed May 04, 2004 is directed to claims 12-14 and 17, the rejection has not been withdrawn.

**[14]** Claim(s) 1, 9-14, 17, 24, and 26-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of fermenting milk by adding a culture of a purine or thymidine auxotrophic bacterial strain to milk and keeping the milk under conditions where the purine or thymidine auxotrophic bacterial strain is metabolically active, but is incapable of DNA replication, RNA transcription, or protein synthesis, wherein if the milk is contaminated with a bacteriophage, the milk is acidified to a pH lower than milk acidified using a corresponding prototrophic bacterial

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strain, does not reasonably provide enablement for the methods as broadly encompassed by claims 1, 9-14, 17, and 24-32. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass methods of fermenting milk by adding a culture of a purine or thymidine auxotrophic bacterial strain to milk and keeping the milk under conditions where the purine or thymidine auxotrophic bacterial strain is metabolically active, including those conditions of being metabolically active and being capable of DNA replication, RNA transcription, or protein synthesis, wherein if the milk is contaminated with a bacteriophage, the metabolic activity of the auxotrophic bacterial strain is substantially unaffected by the



bacteriophage, optionally wherein the method is practiced using a genetically modified strain or a bacterial strain that is capable of increasing cell size without mitosis. The broad scope of claimed methods is not commensurate with the enablement provided by the disclosure with regard to the conditions wherein the culture is metabolically active in milk and the ability of the culture to have a substantially unaffected metabolic activity in the presence of a bacteriophage, genetically modified strains, and bacterial strain that are capable of increasing cell size without mitosis. In this case the disclosure is limited to a method of fermenting milk by adding a culture of a purine or thymidine auxotrophic bacterial strain to milk and keeping the milk under conditions where the purine or thymidine auxotrophic bacterial strain is metabolically active, but is incapable of DNA replication, RNA transcription, or protein synthesis, wherein if the milk is contaminated with a bacteriophage, the milk is acidified to a pH lower than milk acidified using a corresponding prototrophic bacterial strain.

- The lack of guidance and working examples: The specification provides only a single working example of conditions wherein a bacterial culture can ferment milk even in the presence of a bacteriophage, *i.e.*, a purine or thymidine auxotrophic culture that is metabolically active, but is incapable of DNA replication, RNA transcription, or protein synthesis due to the absence of purines or thymidine in the milk. Also, the specification fails to provide even a single working example of a metabolic activity of a bacterial culture that is substantially unaffected by bacteriophage contamination. However, the specification does provide a working example of an activity that is *less* affected than a corresponding prototrophic bacterial culture due to bacteriophage contamination, *i.e.*,

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acidification of milk (see Examples 1 and 2, pages 15-22 of the specification). These working examples fail to provide the necessary guidance for making the entire scope of claimed methods. The specification fails to provide any additional guidance as to conditions that maintain the acidification of milk or metabolic activities that are “substantially unaffected” even in the presence of a bacteriophage. Regarding claims 12-14 and 17, it is noted that the specification fails to disclose even a single working example of genetically modified strains enhanced in at least one metabolic pathway or bacterial strains that are capable of increasing cell size without mitosis.

- The high degree of unpredictability in the art: The conditions under which a bacterial starter culture can be added to milk with an expectation that the culture will maintain metabolic activity while being “substantially unaffected” by a bacteriophage are highly unpredictable, particularly in view of the lack of guidance and working examples in the specification. Similarly, it is highly unpredictable as to the metabolic activity or activities of a bacterial culture that can be maintained in the presence of a bacteriophage, particularly in view of the lack of guidance and working examples in the specification. Also, the ability to genetically modify a bacterium – including those modifications that result in an ability of a bacterium to increase cell size without mitosis – with an expectation of obtaining a bacterium having a desired characteristic is highly unpredictable.
- The amount of experimentation required is undue: It is not routine to screen for all conditions under which a bacterial starter culture will maintain the ability to acidify milk in the presence of a bacteriophage as encompassed by the claims. Also, it is not

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routine to screen the vast number of metabolic activities of a bacterial strain that may or may not be "substantially unaffected" by bacteriophage contamination. Further, it is not routine to screen all genetic modifications of a bacterium as encompassed by the claims for those bacterium that are enhanced in at least one metabolic pathway, enhanced glycolytic flux, enhanced flux through the pentose phosphate pathway, enhanced ATPase activity, or capable of increasing cell size without mitosis.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high degree of unpredictability, and the amount of experimentation required to make the full scope of the claimed invention, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. In this case, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

**[15]** Applicants' arguments addressing the scope of enablement rejection under 35 U.S.C. 112, first paragraph, have been fully considered. As applicants' arguments are directed to the previous scope of enablement rejection that has been withdrawn and do not address the instant scope of enablement rejection, applicants' arguments are moot.


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**Conclusion**

**[16] Status of the claims:**

- Claims 1, 9-14, 17, 24, and 26-32 are pending.
- Claims 1, 9-14, 17, 24, and 26-32 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and on alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

  
David J. Steadman, Ph.D.  
Primary Examiner  
Art Unit 1652